DEPARTMENT OF HEALTH AND HUMAN SERVICE

Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, LA 70127

Telephone: 504-253-4519
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July 2, 2002

WARNING LETTER NO. 2002-NOL-36

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Ed Dalton Barham, M.D., Radiologist
Facility Accreditation Contact
Jackson Healthcare for Women, Professional Association
1047 North Flowood Drive
Jackson, MS 39232

Dear Dr. Barham:

A representative of the State of Mississippi, acting on behalf of the U.S. Food and Drug Administration (FDA), inspected your facility, Jackson Healthcare for Women, Professional Association, located at 1047 North Flowood Drive, Jackson, Mississippi, on May 24, 2002. This inspection revealed serious regulatory problems involving the mammography at your facility.

Under the Mammography Quality Standards Act of 1992 (MQSA), 42 U.S.C. § 263b, and the Quality Standards for Mammography, set forth in Title 21 of the Code of Federal Regulations (CFR) Part 900.12, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 finding at your facility:

- **Phantom QC records were missing for at least four weeks for [redacted] Room Mammo, as required by 21 CFR 900.12 (e)(2).**

The following Level 2 noncompliances were found at your facility:

- **Mammograms were processed in processor 0000000001, [redacted] or [redacted] Room Mammo, when it was out of limits on at least two, but less than five days, as required by 21 CFR 900.12 (e)(8);**

- **Medical audit and outcome analysis was not done for your facility as a whole, as required by 21 CFR 900.12 (f)(1);**

- **Medical audit and outcome analysis was not done separately for each individual physician at your site, as required by 21 CFR 900.12 (f)(1);**

- **Medical audit and outcome analysis was not performed annually at your site, as required by 21 CFR 900.12(f)(2); and**

- **Your facility has no designated audit (reviewing) physician, as required by 21 CFR 900.12 (f)(3).**

The specific problems noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. The problems have been identified as Levels 1 and 2, because they identify a failure to meet significant MQSA requirements that may seriously compromise the quality of mammography services offered by the facility.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents a violation of the law that may result in FDA imposing statutory sanctions without further notice to you. These sanctions include, but are not limited to, placing your facility under a Directed Plan of Correction, and charging your facility for the cost of on-site monitoring. Failure to correct these violations promptly could also cause FDA to seek civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

In addition, the inspection revealed Level 3 findings that were listed on the inspection report provided to your facility at the close of the inspection. The findings are:

- **The compression device QC is not adequate for [redacted] Room Mammo, because the QC tests were not done at the required frequency and, at least once, corrective action before further use was not documented, as required by 21 CFR 900.12 (e)(4)(iii); and**

- **The screen-film contact QC at your site is not adequate, because the QC tests were not done at the required frequency, as required by 21 CFR 900.12 (e)(4)(ii).**

We are very concerned with the practice, during the period of January 2002 through March 2002, whereby [redacted] by your facility QC technician. As you are aware, the purpose of weekly phantom images is to assure the quality of your facility's mammograms.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

- the specific steps you have taken to **correct** the violations noted in this letter;

- each step your facility is taking to **prevent the recurrence** of similar violations; and

- include sample records that demonstrate proper record keeping procedures (Patient names or identification should be deleted from any copies submitted).

Please submit your response to:

Nicole F. Hardin, Compliance Officer
U.S. Food and Drug Administration
6600 Plaza Drive, Suite 400
New Orleans, LA 70127-2601

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to certain findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov.

If you have specific questions about mammography facility requirements, or about the technical contents of this letter, please feel free to contact Ms. Karen R. Smallwood, MQSA Auditor, at (615) 781-5380, extension 144.

Sincerely,

Carl E. Draper
District Director
New Orleans District Office

cc: Priscilla F. Butler, M.S.
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